

EXHIBIT 22

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**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIOID LITIGATION

CITY OF CLEVELAND OHIO and
THE STATE OF OHIO EX REL. ET AL

Plaintiffs,

v.

PURDUE PHARMA L.P., ET AL

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

AMENDED EXPERT REPORT OF SANDRA K.B. KINSEY, R.Ph, MBA.

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experience and achievements, which are more fully set out in my *curriculum vitae*, a copy of which is attached as Exhibit A.

5. I received a Bachelor of Science in Pharmacy in 1992 from the University of Missouri, Kansas City and an MBA from Kaplan University in 2008. I have been a Registered Pharmacist in Kansas since 1992 and became a licensed Pharmacy Doctor in Arkansas in 1996. Both licenses are current, and I actively practice in the state of Arkansas.

6. Until 2014, I was Vice President of Pharmacy Merchandising, Health & Wellness for Walmart, Inc. in Bentonville, Arkansas. I was responsible for all prescription product procurement, preferred formulary development, distribution and supply chain, pricing, and inventory management for over 5,000 stores. During my 17-year career at Walmart, I acquired a breadth of retail pharmacy experience by serving in a variety of roles within Pharmacy Operations, Merchandising, Technology, and Compliance.

7. In 2014, I founded Kinsey Partners, LLC, a retail healthcare consulting firm, where I am currently the president. At Kinsey Partners, I assist industry leaders in developing comprehensive strategies for growth within the retail and healthcare sectors. My contract clients include major retail pharmacies, pharmaceutical companies, and drug wholesalers. I also consult and provide expert opinion through my position at Kinsey Partners.

8. Being a registered pharmacist in Arkansas and Kansas, I also work in stores with independent pharmacists on prescription filling, operational processes, regulatory compliance, technology infrastructure, third party insurance negotiations and billing, customer service, and other related services.

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9. In addition, I am a clinical pharmacist for Highlands Oncology Group, a nationally recognized cancer treatment center. In this position, I regularly care for patients with extensive acute and chronic pain relief needs at various stages of illness.

10. Based on my education, practical training, teaching, research, editorial work, consulting, and industry experience, I consider myself an expert in the areas of retail pharmacy operations, prescription filling, product sourcing, inventory management and supply chain.

B. Prior Testimony and Compensation

11. A copy of my prior expert testimony and work as a subject matter expert is attached as Exhibit B.

12. I have served as an expert on eight cases, with claims including patent infringement, trademark infringement, false advertising, breach of contract, anticompetitive conduct, and antitrust violations. During the past four years, I testified at four trials and I was deposed in the following case(s):

- *Heartland Medical LLC vs. Express Scripts, Inc.*,
Case No. 17CV02873, District Court of Missouri, November 2018
- *Valeant Pharmaceuticals LLC vs. ECI Pharmaceuticals LLC and Virtus Pharmaceuticals LLC*,
Case No. 18CV00355, North District of California
Investigation No. 337TA1109, International Trade Commission, June 2018
- *Takeda Pharmaceuticals Inc. vs. West-Ward and Hikma Pharmaceuticals Inc.*,
Case No. 14CV01268, District Court of Delaware, March 2018
- *Winder Laboratories LLC and Steven Pressman vs. Concordia Pharmaceuticals*,
Case No. 16CV00004, District Court of Georgia, Gainesville Division, April 2018
- *GlaxoSmithKline Inc. vs. Teva Pharmaceuticals Inc.*, Case No. 14CV00878,
District Court of Delaware, December 2016
- *GlaxoSmithKline Inc. vs. Glenmark Pharmaceuticals Inc.*, Case No. 14CV00877,
District Court of Delaware, December 2016

- *Concordia Pharmaceuticals Inc. vs. Winder Laboratories LLC and Steven Pressman*, Case No. 16CV00004, District Court of Georgia, Gainesville Division, March 2016

13. I am being compensated at my customary hourly rate of \$500 for expert consulting on this matter. I expect to be compensated at the same rate for my time spent testifying by deposition or at any hearing. My compensation has not influenced my view on any of my opinions set forth herein and is not dependent on the outcome of the Investigation.

C. Materials Considered and Preparation

14. The opinions and the statements I make in this Report are based on my personal knowledge, education and training, and professional experience. In addition, I rely on and incorporate by reference the documents and information cited in the Report itself and listed in Exhibit C.

D. Assignment

15. I have been asked by counsel to provide an overview of the opioid pharmaceutical market, with concentration on hydrocodone/acetaminophen combination drugs, and the benefits of these products when responding to patient relief of moderate to severe pain. I will also describe the relative role of health care providers, pharmacy dispensing practices, and the benefits of a closed distribution supply chain to not only ensure adequate inventory for patient care, but also to comply with the provisions listed in the Controlled Substances Act to prevent theft and diversion.

16. More specifically, I reviewed the operational infrastructure of Giant Eagle's pharmacy, which consists of a separate and distinct business within a larger grocery chain. I was asked to opine on their systems of integrated controls that have evolved over the years with advancements in technology, physical infrastructures, and general business practices as it relates to compliance with the Controlled Substances Act (CSA).

E. Summary of Expert Opinions

17. Based on my education and experience, information produced in this litigation and publicly available information, I conclude:

- a) As a board licensed pharmacist with over 25 years of experience, I find that opioids are effective and essential drugs for pain management when used appropriately. The vast majority of opioid prescriptions are written for legitimate reasons and consumed by patients according to prescribers' directions without undue or long-lasting harm to the patient.
- b) Patients are increasingly aware of the benefits and risks of pain medications, including opioids. Patients receive verbal and written information from their prescriber and pharmacist that detail precautions and side effects associated with opioid use. Most understand the growing concern surrounding these products and the need to safeguard their personal prescriptions from theft, diversion and misuse.
- c) The first line pharmacologic agent for symptom relief of mild to moderate pain is acetaminophen (Tylenol™) or a non-steroidal anti-inflammatory drug (Motrin™/ibuprofen). If pain is not resolved or is expected to be moderate to severe intensity, evidence-based treatment protocols recommend opioid/acetaminophen combination products.¹ As the mildest

¹ Bondell, R., Azadfar, M., and Wisniewski, A. Pharmacologic Therapy for Acute Pain. *American Family Physician*. 2013 Jun 1;87(11):766-772, available at <https://www.aafp.org/afp/2013/0601/p766.html> (last accessed May 3, 2019).

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dose, hydrocodone containing products (HCP), like Norco™, are the most frequently prescribed drugs for pain relief.²

- d) Pharmacies play an essential role in patient care. Besides dispensing prescriptions, pharmacists are an integral part of the communication process between doctor, manufacturer, insurer, regulatory agencies and patient, ensuring efficacy, safety and access to every drug they dispense for every patient to which they extend care.
- e) Prescriptions are written and dispensed by highly educated, licensed health care providers that complete annual certifications for practice by their respective state governing boards. Distributors and pharmacies are licensed by state and federal authorities and are inspected yearly for compliance to all legal regulations. These key stakeholders regularly receive and complete compliance training that details procedures for the prevention of theft and diversion of opioid prescriptions.
- f) As part of the prescription filling process, a pharmacist often communicates with prescribers regarding an opioid prescription to discuss the drug, strength, dose or frequency of utilization for a specific patient. Referencing information from a patient's insurance company, national and state opioid databases, or through experience, a pharmacist may refuse to fill a prescription that appears inappropriate based on their professional judgment.

² Hydrocodone (2018). Drug Enforcement Administration Diversion Control Division, available at https://www.deadiversion.usdoj.gov/drug_chem_info/hydrocodone.pdf (last accessed May 4, 2019).

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g) The Controlled Substances Act (CSA) requires all applicants and registrants to provide effective controls and procedures to guard against theft and diversion (the “Security Requirement”)³. Substantial compliance with the Security Requirement is based upon an overall evaluation of the security system and needs of the registrant using a combination of factors including: the type of activity conducted; the type, form and quantity of controlled substances handled; the type and location of the facility; the types of secure enclosures; detection and alarm systems; and the adequacy of the registrant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations. The DEA has left it substantially to the discretion of each registrant to design and operate its system to comply with the Security Requirement, and such system must be able to disclose suspicious orders when discovered⁴. Policies and procedures for compliance with all requirements of the CSA have evolved over the years and will continue to change with advancements in technology, physical infrastructures, and general business practices.

h) Captive self- distributors for prescription products fulfill orders that will replenish shelf stock for items that have already been dispensed. Therefore, artificially limiting order quantities, preventing shipments and delaying orders unnecessarily can interrupt patient care and cause further harm.

³ 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.71.

⁴ 21 C.F.R. §§ 1301.74.

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- i) Giant Eagle is a small grocery chain with a relatively small pharmacy business. Recognizing the complex differences to the core organization, Giant Eagle built a pharmacy infrastructure that is separate from its main grocery business in order to focus on patient care, prescription delivery and cost, supply chain, regulatory compliance, training and other health related business services. This independence enables the pharmacy to operate with efficiency and accuracy because of the redundant layers of oversight by specially trained and educated employees.
- j) Giant Eagle's inventory management system consists of integrated controls within the corporate office, distribution center and pharmacy to prevent theft and diversion of all prescription products. Because of the heightened sensitivity concerning controlled substances, and opioids in particular, additional parameters are engaged that exceed regulatory minimums.
- k) Giant Eagle is, and always has been, compliant with the Controlled Substances Act as evident by their continued licensing by the Ohio State Board of Pharmacy, the Pennsylvania, West Virginia, Maryland and Indiana State Boards of Pharmacy and the Drug Enforcement Agency for every store in the respective states as well as for the HBC Services Company (HBC) and Giant Eagle Rx (GERx) distribution centers. Because of their robust and cohesive processes to prevent theft and diversion before it occurs, it is not surprising that only a limited number of

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orders were identified as part of their comprehensive design of SOM systems and safety controls.

II. OVERVIEW OF THE OPIOID MARKET

A. A Brief Review of Opioids and the Controlled Substances Act

18. Opioids have been regarded for millennia as among the most effective drugs for the treatment of pain.⁵ Opioids are a group of narcotic pain-relieving drugs which act by interacting with opioid receptors in the brain, spinal cord and other areas of the body to interrupt the pain response pathway. Opioids can be made from the poppy plant, such as morphine, or synthesized in a laboratory, such as fentanyl. Opioids are used as an anesthesia, cough suppressant, diarrhea suppressant and for the management of pain arising from various diseases and injuries.⁶ According to the National Institutes of Health, a division of the U.S. Department of Health and Human Services (HHS), opioids are “generally safe when used for a short time and as prescribed by a doctor.”⁷

19. According to research from 2016, the opioid market is witnessing growth due to increasing prevalence of orthopedic diseases and other chronic pain afflictions, rising focus on abuse-deterrent formulations, growth of palliative care initiatives and facilities, and an inclination toward extended release formulations from the immediate release alternatives.⁸

⁵ Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology*, 16(5), 405-416, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/> (last accessed May 3, 2019).

⁶ Opioids Market by Product (Morphine, Codeine, Fentanyl, Meperidine), Receptor Binding (Strong Agonist, Mild to Moderate Agonist), Application (Pain Management, Cough Suppression, Diarrhea Suppression), Region (North America, Europe, Asia, RoW) – Global Forecasts to 2023, available at <https://www.marketsandmarkets.com> (last accessed May 3, 2019).

⁷ How Opioid Drugs Activate Receptors (2018), available at <https://www.nih.gov/news-events/nih-research-matters/how-opioid-drugs-activate-receptors> (last accessed May 3, 2019).

⁸ Opioids Market by Product (Morphine, Codeine, Fentanyl, Meperidine), Receptor Binding (Strong Agonist, Mild to Moderate Agonist), Application (Pain Management, Cough Suppression, Diarrhea Suppression), Region (North America, Europe, Asia, RoW) – Global Forecasts to 2023, available at <https://www.marketsandmarkets.com> (last accessed May 3, 2019).

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However, factors such as prescription drug abuse and misuse and the corresponding increases in regulations will create offsets as prescribing authority and insurance reimbursements are limited. The unintended consequence of these restrictive regulations also impacts patient care by creating additional complexity to access and treatment, forcing patients to suffer or seek medication from illegal sources.

20. Recognizing the harm caused by certain drugs and the need to consolidate more than 200 separate laws, President Richard Nixon signed the Controlled Substances Act (CSA) in 1970, combining all prior existing federal drug laws into one consistent statute.⁹ The CSA is administered and enforced by the Drug Enforcement Agency (DEA) and it regulates the manufacture and distribution of controlled substances and categorizes drugs into five classifications or “schedules” based on, *inter alia*, their medical significance and potential for abuse.¹⁰

21. Schedule I drugs are deemed to have no currently accepted medical value and a high potential for abuse. Examples include heroin, LSD and ecstasy.

22. Schedule II drugs provide medical value and a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Some examples include cocaine, methamphetamine, oxycodone, and fentanyl.

23. Substances with progressively less potential for harm and abuse were placed in Schedules III through V respectively.

24. When Congress passed the CSA in 1970, it placed hydrocodone containing products (HCPs) in Schedule III. However, after more than 40 years, due to the many findings

⁹ Van Dusen, V. and Spies, A. An Overview and Update of the Controlled Substances Act of 1970. Pharmacy Times (2007), available at <https://www.pharmacytimes.com/publications/issue/2007/2007-02/2007-02-6309> (last accessed May 3, 2019).

¹⁰ 21 U.S.C. § 812 and 21 C.F.R. §§ 1301.

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by the Drug Enforcement Administration (DEA) and the United States Department of Health and Human Services (HHS), HCP was eventually moved into Schedule II in 2014 in response to the ever-growing problem of abuse and misuse.¹¹

25. Today, experts say the United States is in the throes of an opioid epidemic. According to the Centers for Disease Control and Prevention, from 1999 to 2017, almost 400,000 people died from an overdose involving opioids, including prescription and illicit opioids¹². Referencing Table 1, this rise in overdose deaths can be outlined in three distinct waves:

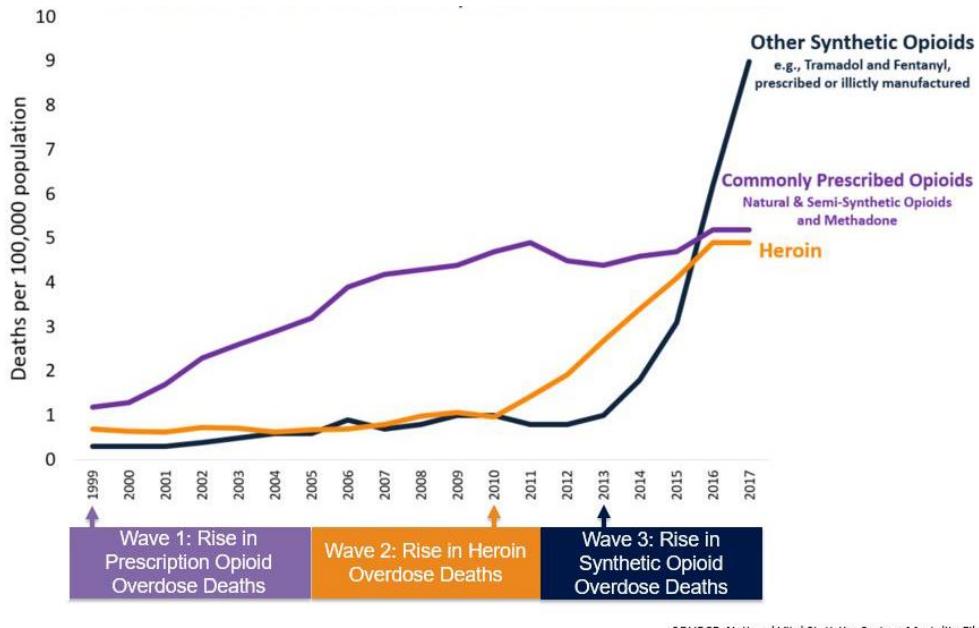
- (i) The first wave began with increased prescribing of opioids in the 1990s, with overdose deaths mainly involving prescription opioids.
- (ii) The second wave began in 2010, with rapid increases in overdose deaths involving heroin.
- (iii) The third wave began in 2013, with significant increases in overdose deaths involving synthetic opioids – particularly those involving illicitly manufactured fentanyl.¹³

¹¹ DEA To Publish Final Rule Rescheduling Hydrocodone Containing Products (2014). United States Drug Enforcement Administration, available at <https://www.dea.gov/press-releases/2014/08/21/dea-publish-final-rule-rescheduling-hydrocodone-combination-products> (last accessed May 3, 2019).

¹² Opioid Overdose. Understanding the Epidemic. Centers for Disease Control and Prevention, available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last accessed May 3, 2019).

¹³ Opioid Overdose. Understanding the Epidemic. Centers for Disease Control and Prevention, available at <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last accessed May 3, 2019).

Table 1: The Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

26. Opioids play a unique role in society. The Food and Drug Administration (FDA) comprehensively regulates prescription drugs in the United States. Although the FDA has approved and continues to approve opioids for efficacy and safety, they have become widely feared compounds by healthcare providers and patients, not because of concerns for the active chemical compound and related side effects, but because of the association with abuse, addiction and the dire consequences of diversion. These drugs are also essential medications and the most effective drugs for the relief of pain and suffering.¹⁴

27. According to the DEA, the overwhelming majority of prescribers act responsibly with regards to opioid prescriptions and that 99.5% of prescribers do not overprescribe these medications.¹⁵

¹⁴ Rosenblum, A., Marsch, L. A., Joseph, H., & Portenoy, R. K. (2008). Opioids and the treatment of chronic pain: Controversies, current status, and future directions. *Experimental and Clinical Psychopharmacology, 16*(5), 405-416, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/> (last accessed May 3, 2019).

¹⁵ Deposition of Thomas Provoznik, dated April 17-18, 2019, pp. 400-403 and 436-441.